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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,604	01/11/2001	Roy Luedtke JR.	1333	9610

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,604

Applicant(s)

LUEDTKE, ROY

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 January 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-49 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claim Objections

1. Claims 8 and 27 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 8 has been interpreted as if the recitation "the inbred maize plant of claim 2" read --the plant of inbred line PH3PV--. Claim 27 has been interpreted as if "the inbred maize plant of claim 21" read --the maize plant having all the physiological and physiological characteristics of inbred line PH3PV--.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,124,534 ('534). Although the conflicting claims are not identical, they are not patentably distinct from each other because

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they both appear to be drawn to the same maize seeds, plants, plant parts and methods. The instantly claimed plants and the patented plants have different designations. The designation "PH3PV" of the instantly claimed cultivar is arbitrarily assigned, and does not provide any patentable distinction from the cultivar claimed in '534, PH1K2. Any differences between PH3PV and PH1K2 are due to minor morphological variations that do not confer patentable distinction. The instantly claimed plants that are derived from crosses and breeding programs involving PH3PV or plants having the same morphological and physiological characteristics of PH3PV, and plants produced by genetic transformation of PH3PV, are not patentably distinct from the patented plants that are derived from crosses and breeding programs involving PH1K2 or plants having the same morphological and physiological characteristics of PH1K2, and plants produced by genetic transformation of PH1K2. The instantly claimed methods are also not patentably distinct from the patented methods, as the plants used in the methods are not patentably distinct, and involve the same steps. The claims of '534 include a method of producing a maize plant comprising crossing a maize plant, having all the morphological and physiological characteristics of PH1K2 wherein the plant has been transformed with a transgene, with a non-transformed plant of line PH1K2. As the transgene would be transferred to the non-transformed plant, and as the transgene would affect a plant trait, it is obvious that this plant product of this cross can be considered as comprising a single gene conversion. A patent issuing from the instant application would then effectively extend the term of the claims of '534.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "PH3PV" in claims 1, 6,^{12,} 14, 21, 25,^{31,} 33, 37, 40-42, and 44-46 render the claims and those dependent thereon indefinite. Since the name "PH3PV" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "PH3PV" does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and the specific characteristics associated therewith could be modified. The missing ATCC accession number in claims 1, 6, 21, 25, 37, and 40 also renders the claims indefinite, as the claims do not clearly identify the deposited seed. Amending claims 1, 6, 21, 25, 37, and 40 to recite the ATCC deposit number in which seed of corn inbred line PH3PV has been deposited would overcome the rejection.

In claims 14, 33, 41, 45, and 46: the terms "high," "early," and "good," are relative terms that have no definite meaning. The terms do not reasonably apprise one of the scope of the invention. The recitation "high yield" also renders the claims indefinite because it is not clear what kind of yield, for example silage, pollen, grain, etc., is being referred to. The recitation "Northcentral region of the United States" also renders the claims indefinite. It is not exactly clear what states or geographic areas make up this region. It is also not clear what exactly is meant by "dry land agriculture, short growing season".

In claims 16 and 35: the claims are indefinite for improper antecedent basis. The claims indicate that they are directed to the corn plant breeding program of claims 15 and 35, respectively. However, claims 15 and 35 are directed to methods, not programs. It is suggested that the recitation "corn plant breeding program" in line 1 of claims 16 and 35 be replaced with -- method--.

In claims 18, 19, 48, and 49: the claims are indefinite for improper antecedent basis. The claims indicate that they are directed to the single gene conversion(s) of claims 18 or 47. However, claims 18 and 47 are directed to maize plants.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3, 9-14, 17-20, 22, 28-33, 36-39, 41-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a corn plant produced by growing seed of any corn inbred line designated PH3PV, or a corn plant having all the morphological and physiological characteristics of corn plant PH3PV wherein said plants are male sterile; any F₁ hybrid corn seed

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produced by crossing corn plant PH3PV with any other inbred corn plant; any F₁ hybrid corn plant produced by growing said hybrid corn seed; any maize plant wherein at least one ancestor is PH3PV and expresses a combination of at least two PH3PV traits; any PH3PV-derived corn plant produced by crossing PH3PV with any other corn plant from 0-7 times; or the corn plant grown from PH3PV seed, wherein the plant has been transformed so that its genetic material contains one or more transgenes operably linked to regulatory elements, and progeny thereof; a method for producing a maize plant comprising crossing said PH3PV plant that comprises one or more transgenes; any corn plant or parts thereof, produced in a method for developing a corn plant in a plant breeding program wherein PH3PV is a source of breeding material; any PH3PV plant that further comprises any single gene conversion(s); a process for producing inbred line PH4PV comprising planting a collection of PH3PV hybrid seed and PH3PV itself; a method of producing PH3PV-derived plant comprising crossing PH3PV with another maize plant, or wherein said method further comprises plant tissue culture methods, or wherein the PH3PV-derived plant is crossed from 0 to 5 times to generate further PH3PV-derived plants.

The specification describes morphological and physiological traits of an inbred corn plant arbitrarily designated "PH3PV" (page 17, line 3 to page 20, line 50; page 35, line 28 to page 37, line 9; page 39, line 1 to page 49, line 30). The specification also indicates that hybrid plants were produced by crossing PH3PV to a corn plant designated PH5TG. Numerous traits of the PH5TG/PH3PV hybrid were compared to hybrid plants produced by crossing corn plants PHAA0 to PHTD5, PHRE1 to PHTD5, PH47A to PHTD5, and PHTD5 to PH185 (page 37, line 10 to page 38, line 34; page 50, line 1 to page 53, line 58). The specification further indicates that upon allowance of any claims, all restrictions on the availability to a deposit of 2500 seeds

of PH3PV with the American Type Culture Collection will be irrevocably removed and all requirements of 37 CFR 1.801-1.809 will be met (page 54, lines 2-21).

However, the specification does not describe PH3PV as being male sterile. The specification discusses how plants may be manipulated to be male sterile (page 2, line 21 to page 3, line 14). However, the morphological and physiological description of plant PH3PV described in the specification does not indicate that it is male sterile.

The specification also does not describe the plants produced by the corn breeding programs, transgenic PH3PV plants, PH3PV plants comprising single gene conversion(s), or by crosses wherein at least one ancestor is corn variety PH3PV, other than PH5TG/PH3PV. The morphological and physiological traits of the corn plants that are crossed with PH3PV, and with progeny of that cross, are unknown, and the description of progeny and descendants of corn plant PH3PV are unknown. The description of corn plant PH3PV is not indicative of the description of plants and seed produced by the breeding programs and crosses, or of any of its descendants. The claimed invention also encompasses plants that express at least two of the "PH3PV traits" listed in claims 14, 33, 41, 45, and 46. However, to say that a plant expresses two traits of another plant is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as those expressed by PH3PV. Two plant traits do not provide any description of the other traits of a plant. It is possible that the claimed plants inherited the genes governing those traits from an ancestor other than plant PH3PV. For example, Kramer (U. S. Patent No. 6,124,534) describes a corn plant, designated "PH1K2," which has at least two traits in common with PH3PV, early flowering, good root lodging resistance, and good stalk lodging resistance, for example (col. 10, line 59 to col. 11, line 5). The instantly claimed corn plants

could have PH1K2 as an ancestor, as well as PH3PV, in which the early flowering and good root lodging resistance traits, for example, could have been inherited from PH1K2. The claims also encompass plants that do not have to express any of the traits that are expressed by PH3PV. The specification does not describe any of the traits of such plants, and the morphological and physiological description of PH3PV is not indicative of the description of such plants. The description of the PH5TG/PH3PV hybrid also does not provide any information concerning the description of any other hybrids. The morphological and physiological traits of PH5TG/PH3PV are not indicative of the traits expressed by other hybrids. The descriptions of PH3PV and PH5TG/PH3PV are also not indicative of any transgenic plant or PH3PV plants comprising single gene conversion(s). The transgene may be of any gene, including those that effect more than one trait. The morphological and physiological characteristics of any such plant are not described. The specification also does not describe single gene conversions for all plant traits. Given the breadth of the claims encompassing corn plant PH3PV having male sterility, corn plants expressing at least two traits that are also expressed by PH3PV, or any trait, and descendants of PH3PV, and lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

5. Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a corn plant produced by growing seed of any corn inbred line designated PH3PV, or a corn plant having all the morphological and physiological characteristics of corn plant PH3PV; or wherein said plants are male sterile; tissue culture of regenerable cells from said plants; a maize plant regenerated from said tissue culture capable of expression all the morphological and physiological characteristics of PH3PV; method for producing a F₁ hybrid maize seed comprising crossing PH3PV with a different inbred maize plant; any F₁ hybrid corn seed produced by crossing corn plant PH3PV with any other inbred corn plant; any F₁ hybrid corn plant produced by growing said hybrid corn seed; any maize plant wherein at least one ancestor is PH3PV and expresses a combination of at least two PH3PV traits; any PH3PV-derived corn plant produced by crossing PH3PV with any other corn plant from 0-7 times; or the corn plant grown from PH3PV seed, wherein the plant has been transformed so that its genetic material contains one or more transgenes operably linked to regulatory elements, and progeny thereof; a method for producing a maize plant comprising crossing said PH3PV plant that comprises one or more transgenes; any corn plant or parts thereof, produced in a method for developing a corn plant in a plant breeding program wherein PH3PV is a source of breeding material; any PH3PV plant that further comprises any single gene conversion(s); a process for producing inbred line PH4PV comprising planting a collection of PH3PV hybrid seed and PH3PV itself; a method of producing PH3PV-derived plant comprising crossing PH3PV with another maize plant, or wherein said method further comprises plant tissue culture methods, or wherein the PH3PV-derived plant is crossed from 0 to 5 times to generate further PH3PV-derived plants.

Since the claimed seed of maize inbred line PH3PV is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public.

If the seeds are deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (e) the invention was described in-
- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-49 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kramer (U.S. Patent No. 6,124,534).

The claims are broadly drawn towards a corn plant produced by growing seed of any corn inbred line designated PH3PV, or a corn plant having all the morphological and physiological characteristics of corn plant PH3PV; or wherein said plants are male sterile; tissue culture of regenerable cells from said plants; a maize plant regenerated from said tissue culture capable of

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expression all the morphological and physiological characteristics of PH3PV; method for producing a F₁ hybrid maize seed comprising crossing PH3PV with a different inbred maize plant; any F₁ hybrid corn seed produced by crossing corn plant PH3PV with any other inbred corn plant; any F₁ hybrid corn plant produced by growing said hybrid corn seed; any maize plant wherein at least one ancestor is PH3PV and expresses a combination of at least two PH3PV traits; any PH3PV-derived corn plant produced by crossing PH3PV with any other corn plant from 0-7 times; or the corn plant grown from PH3PV seed, wherein the plant has been transformed so that its genetic material contains one or more transgenes operably linked to regulatory elements, and progeny thereof; a method for producing a maize plant comprising crossing said PH3PV plant that comprises one or more transgenes; any corn plant or parts thereof, produced in a method for developing a corn plant in a plant breeding program wherein PH3PV is a source of breeding material; any PH3PV plant that further comprises any single gene conversion(s); a process for producing inbred line PH4PV comprising planting a collection of PH3PV hybrid seed and PH3PV itself; a method of producing PH3PV-derived plant comprising crossing PH3PV with another maize plant, or wherein said method further comprises plant tissue culture methods, or wherein the PH3PV-derived plant is crossed from 0 to 5 times to generate further PH3PV-derived plants.

Kramer teaches seed of an inbred maize line designated "PH1K2," plants produced by growing said seed, and plants and plant parts having all of the physiological and morphological characteristics of PH1K2 (col. 10, line 59 to col. 13, line 50). It appears that the claimed plants and seeds of the instant invention may be the same as PH1K2, given that they exhibit similar traits, such as early flowering and good root lodging and stalk lodging resistances, for example

(col. 10, line 59 to col. 11, line 5). Alternatively, if the claimed plants, plant parts, and seeds of PH3PV are not identical to PH1K2, then it appears that PH1K2 only differs from the instantly claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to PH3PV. Kramer also teach methods to confer male sterility and plant PH1K2 where it is further male sterile; production of tissue culture of regenerable cells from a plant of line PH1K2, wherein regenerable cells are from tissues including flowers, pollen, ovules, among others; a plant produced from tissue culture of PH1K2 that is capable of expressing all of the morphological and physiological traits of PH1K2; methods for producing hybrid seeds and plants wherein a plant of inbred line PH1K2 is crossed with another inbred corn plant, and the ensuing seed are harvested, or wherein the method further comprises utilizing plant tissue culture methods to derive progeny; corn plant breeding programs, including backcrossing, pedigree breeding, recurrent selection, among others; method for producing PH1K2 inbreds comprising planting a collection of seed of PH1K2 and a hybrid, one of whose parents is PH1K2, and identifying inbred PH1K2 by decreased vigor or identifying seed or the inbred plants with homozygous genotype; PH1K2 comprising transgenes operably linked to regulatory elements, introduced via genetic engineering or breeding, as well as crossing the transformed plant with another plant to produce progeny comprising the inherited transgene; and crossing two corn plants wherein either one or both parents is PH1K2, and crossing the resultant plant with itself or another corn plant to derive further progeny, and repeating such crossing 0 to 5 times; and an F₁ hybrid produced by crossing PH1K2 with inbred PH1W2 (col. 2, line 4 to col. 4, line 22; col. 13,

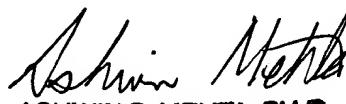
line 55 to col. 14, line 19; col. 14, line 60 to col. 23, line 3; col. 24, line 45 to col. 25, line 3; claims). Note that the plants produced by crossing a transformed PH1K2 plant with a non-transformed PH1K2 plant produced a PH1K2 plant with a single gene conversion. It was obvious that the transferred gene could have been a dominant or recessive allele of a gene. The claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Kramer.

7. No claim is allowed.

Contact Information

Any inquiry concerning this communication from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

June 2, 2002


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER